**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| **IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION** | MDL No. 2875<br><br>Honorable Robert B. Kugler, District Court Judge<br><br>Honorable Thomas Vanaskie (Ret.), Special Discovery Master<br><br>**[PROPOSED] ORDER GRANTING MOTION TO SEAL PURSUANT TO L.CIV.R. 5.3(c)** |

THIS MATTER having been brought before the Court by way of the Motion to Seal Exhibits 4-10 and 14-16 to Plaintiffs' Plaintiffs' Motion to Compel the ZHP Parties' Supplemental Production (the "Motion to Compel") (ECF. No. 1405) pursuant to Local Civil Rule 5.3(c) (the "Motion to Seal") filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Prinston Pharmaceutical Inc. ("Prinston"), Huahai U.S. Inc. ("Huahai U.S."), and Solco Healthcare U.S., LLC ("Solco," and collectively with ZHP and Prinston, "the ZHP Parties") on notice to liaison counsel for Plaintiffs; and the Court having considered the parties' submissions and proposed documents requested to be sealed, and the criteria contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the

standards set forth in Local Rule 5.3(c)(2) have been met, the Court makes the following Findings of Fact and Conclusions of Law:

## FINDINGS OF FACT

1. Through discovery in this case, the ZHP Parties have produced confidential information, the public disclosure of which would affect the ZHP Parties' legitimate business interests and competitive standing. To protect the confidentiality of information produced in discovery in this case, the parties negotiated and agreed to maintain the confidentiality of any materials produced pursuant to the Confidentiality and Protective Order (the "Protective Order"), entered by the Honorable Robert B. Kugler on June 26, 2019 (ECF. No. 139).

2. The Protective Order permits the producing party to safeguard information by designating a document either "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION."

3. The Protective Order defines the type of information that warrants a confidentiality designation:

> The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith

> to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.
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> "RESTRICTED CONFIDENTIAL INFORMATION" means Documents that a Party has designated as "RESTRICTED CONFIDENTIAL" in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including **proprietary manufacturing and production information (including formulation)**; business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm . . .

(ECF. No. 139, ¶¶ 9(B), (M)) (emphasis added).

4. The Protective Order also takes a pragmatic view of confidentiality designations given the size and scope of this litigation.

> It is anticipated that the volume of documents to be exchanged by the parties during pre-trial discovery may be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as "CONFIDENTIAL INFORMATION" in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions . . . .

(*Id.* at ¶ 9(B)).

5. This is particularly true where, as here, the ZHP Parties are competitors not only with the other manufacturer defendants in this MDL, but also with

companies not included in this MDL, in the highly competitive generic drug marketplace. The Protective Order is designed to ensure that documents properly designated as either "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" are not subject to unfettered disclosure to protect the parties from the risk of significant competitive harm.

6. Pursuant to the Protective Order, a party may designate a document as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION," and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. *Id.* at ¶¶ 22, 24.

7. On July 23, 2021, Plaintiffs filed the Motion to Compel (ECF. No. 1405), which attached as exhibits seventeen documents designated by the ZHP Parties as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" under the Protective Order. *See* Bonner Decl. at ¶ 3. Plaintiffs subsequently challenged the ZHP Parties' confidentiality designations as to these seventeen exhibits. *See id.*

8. The parties agreed to extend the deadline for the ZHP Parties to resolve Plaintiffs' challenges or otherwise file a motion to seal the exhibits is October 12, 2021. *See id.* at ¶ 4.

9. Following careful review of the seventeen challenged exhibits, the ZHP Parties have affirmatively agreed to de-designate seven exhibits as not confidential (Exhibits 11-13, 17-19, 28).[2] *See id.* at ¶ 6.

10. The ZHP Parties cannot agree to de-designate the remaining ten exhibits because they (1) implicate third party privacy interests protected by confidentiality agreements with those third parties; or (2) disclose proprietary, non-public testing information that would be of significant competitive value to the ZHP Parties' competitors. *See id.* at ¶ 7.

11. Because these ten exhibits were designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" pursuant to Paragraphs 9 (B) and (M) of the Protective Order, the ZHP Parties formally move to seal the following exhibits pursuant to Paragraph 31 of the Protective Order, as well as Local Civil Rule 5.3(c):

a. **ZHP02471924** (ECF No. 1405, Ex. 4) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): A letter from one of the ZHP Parties' customers, Novartis International Pharmaceuticals Ltd., Branch Ireland ("NIPBI"), to ZHP employees dated July 19, 2018, regarding the return of valsartan API

[2] The ZHP Parties have requested, and Plaintiffs consented to, a redaction of an account number contained in Exhibit 17 pursuant to Fed. R. Civ. P. 5.2(a). *See* Bonner Decl. at n. 4.

delivered to NIPBI, which is subject to a mutual confidential disclosure agreement between NIPBI and the ZHP Parties. *See* Index at 1 (citing Xu Decl. ¶¶ 3-5).

b. **ZHP02734637** (ECF No. 1405, Ex. 5) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): A duplicate of ZHP02471924 (ECF No. 1405, Ex. 4), described in the paragraph above. *See id.*

c. **ZHP02490581** (ECF No. 1405, Ex. 6) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): A letter from Sandoz AG and Sandoz Pvt. Ltd. to ZHP employees dated January 15, 2019 regarding a notification of claims and actions involving the affiliates of Sandoz Pvt. Ltd. and Sandoz AG (collectively, "Sandoz") related to the ZHP Parties' product, which was not intended for the U.S. market, and is subject to a confidentiality provision in the API supply agreement between Sandoz and the ZHP Parties. *See* Index at 2 (citing Xu Decl. ¶¶ 7-9).

d. **ZHP02735368** (ECF No. 1405, Ex. 7) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): A duplicate of ZHP02490581 (ECF No. 1405, Ex. 6), described in the paragraph above. *See id.*

e. **ZHP02731217** (ECF No. 1405, Ex. 8) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): Non-public, internal communications between ZHP employees dated January 13, 2018 regarding testing of the ZHP Parties' irbesartan intermediate compounds, which describes non-public, proprietary

testing practices and procedures unrelated to the claims at issue in this litigation. *See* Index at 3 (citing Li Decl. ¶ 3).

f. **ZHP00180427** (ECF No. 1405, Ex. 9) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): Emails dated April 28 through May 3, 2017 between employees from the ZHP Parties and those of the ZHP Parties' customer, MacLeods Pharmacy, regarding chromatography testing of the ZHP Parties' valsartan KSM, which were subject to a mutual confidential disclosure agreement between the ZHP Parties and MacLeods Pharmacy, and continuing confidentiality obligations pursuant to the relevant purchase order terms and conditions. *See* Index at 4 (citing Xu Decl. ¶¶ 11-14).

g. **ZHP02628144** (ECF No. 1405, Ex. 10) (designated "CONFIDENTIAL INFORMATION"): Non-public communications between the ZHP Parties and a potential business partner from November-December 2017 regarding a draft valsartan synthesis process development contract, in which the ZHP Parties and their intended business partner discuss proposed revisions to the draft agreement prior to its implementation, including whether the agreement should include four pharmaceutical products not related to valsartan, and whether their intended business partner has the technical capability to include the additional products subject to the ZHP Parties' specifications, as well as considerations for

future collaborations and material cost calculations. *See* Index at 5 (citing Xu Decl. ¶¶ 16-17).

h. **ZHP02710347** (ECF No. 1405, Ex. 14) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): An investigation report prepared by the ZHP Parties, which details proprietary specifications and testing methods for impurities related to irbesartan and unrelated to the claims at issue in this litigation. *See* Index at 6 (citing Li Decl. ¶ 4).

i. **ZHP02710344** (ECF No. 1405, Ex. 15) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): Internal, non-public pilot test results from May 2, 2017 to August 10, 2017 that detail the ZHP Parties' proprietary specifications and testing methods for impurities in irbesartan. *See* Index at 7 (citing Li Decl. ¶ 5).

j. **ZHP02710242** (ECF No. 1405, Ex. 16) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): Internal, non-public experiment results regarding the testing and validation of irbesartan samples from August 21, 2017 to December 29, 2017 that detail the ZHP Parties' proprietary specifications and testing methods for impurities in irbesartan. *See* Index at 10 (citing Li Decl. ¶ 6).[3]

[3] Likewise, Plaintiffs have redacted a sentence of their Motion to Compel that discloses confidential information contained in Exhibits 14-16. *See* Mot. to Compel at 1, 9 (ECF No. 1405). Because the ZHP Parties seek to seal Exhibits 14-16 in their

12. The above-referenced documents generally fall into three (3) categories of non-public information:

a. Confidential customer communications designated "RESTRICTED CONFIDENTIAL INFORMATION" that contain non-public and commercially sensitive information that are subject to confidentiality agreements (Exhibits 4, 5, 6, 7, and 9) (the "Category 1 Documents");

b. Confidential communications with potential business partners regarding the negotiation and drafting of a potential contract designated "CONFIDENTIAL INFORMATION" (Exhibit 10) (the "Category 2 Document");

c. Internal communications that disclose the ZHP Parties' proprietary testing processes related to irbesartan, which have been designated "RESTRICTED CONFIDENTIAL INFORMATION" (Exhibits 8, 14, 15, 16) (the "Category 3 Documents").

13. These documents contain non-public commercial, financial, and proprietary information, which is believed in good faith by the ZHP Parties to have the potential, if disclosed, for causing significant competitive harm to them in the

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entirety, for the same reasons described herein, the ZHP Parties respectfully seek to maintain that redaction.

form of decreased market share, damaged customer relationships, litigation costs and contract damages and/or injunctive relief.

## CONCLUSIONS OF LAW

14. Courts have recognized that the presumption of public access is not absolute and may be rebutted. *See In re Avandia Mktg., Sales Practices & Prods. Liability Litig.*, 924 F.3d 662, 672 (3d. Cir. 2019). The party seeking to overcome the presumption of access must show "'that the interest in secrecy outweighs the presumption.'" *Avandia*, 924 F.3d at 672 (3d Cir. 2019) (quoting *Bank of Am. Nat'l Tr. & Say. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). To do so, the movant must demonstrate "'that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.'" *Id.* (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)); *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984)); *Pansy*, 23 F.3d at 787. The Court must then determine if the harm from the articulated injury outweighs the presumption of access. *Pa. Nat'l Mut. Casualty Ins. Grp. v. New Eng. Reins. Corp.*, 840 F. App'x 688, 690 (3d Cir. 2020).

15. Under Local Rule 5.3(c) governing the standards that a motion to seal must satisfy, documents may be filed and maintained under seal upon a showing of good cause. *See* D.N.J. L. Civ. R. 5.3(c); *Vista India, Inc. v. Raaga, LLC*, No. 07-cv-1262, 2008 WL 834399, at *3 (D.N.J. Mar. 27, 2008). The moving party must

show that the following factors weigh in favor of sealing the information at issue: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available. *See* D.N.J. L. Civ. R. 5.3(c)(3). This Court has discretion in balancing the factors for and against access to court documents. *See Pansy v. Stroudsburg*, 23 F. 3d 772, 791 (3d Cir. 1994).

16. Factors weighing in favor of confidentiality are: (1) the information to be protected includes genuinely confidential information such as proprietary materials, or information that could give unfair advantage to a competitor; (2) the documents were produced under the auspices of an existing confidentiality order upon which the parties relied; (3) the materials are not subject to freedom of information laws or statutes requiring disclosure of public documents; and (4) the party to benefit from the order is a private entity, not a public official seeking protection from "legitimate public scrutiny." *Pansy*, 23 F.3d at 788-91. The scale is tipped in favor of confidentiality where the parties relied on a prior confidentiality order. *See, e.g.*, *Rutigliano v. Appleton Papers, Inc.*, No. 90-1432, 2000 WL 1705152 at *5 (D.N.J. Oct. 6, 2000) (public disclosure in product liability action should not be compelled where defendant produced material in reliance on a confidentiality order).

17. As set forth below, the ZHP Parties satisfy the criteria for sealing set forth in Local Rule 5.3(c) as to each category of challenged exhibits.

**A. The ZHP Parties' Legitimate Interest in Maintaining the Confidentiality of Exhibits 4, 5, 6, 7, and 9 Because They Implicate Third Party Privacy Concerns (the Category 1 Documents)**

18. Exhibits 4, 5, 6, 7, and 9 are communications with the ZHP Parties' customers that have been designated "RESTRICTED CONFIDENTIAL INFORMATION" because they contain non-public and commercially sensitive information obtained through the ZHP Parties' business relationships with their customers, and are subject to confidentiality agreements restricting their dissemination without prior authorization or a court order.

19. As this Court has recognized, the ZHP Parties have a legitimate interest in maintaining the confidentiality of customer communications, particularly where the customers themselves clearly intended to restrict the distribution of their communications to the intended recipients. *See In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.,* MDL No. 2875, dated May 24, 2021 at 9-10 (the "May 24, 2021 Order") (granting motion to seal supplier report subject to a confidentiality agreement where "the third party's designation of the document as confidential coupled with ZHP's representation that disclosure would harm its relationship with the third party suffice to overcome the presumption of public access.").

20. As described in the Xu Declaration, all of the Category 1 exhibits are subject to robust confidentiality provisions or confidential disclosure agreements with the ZHP Parties' customers. *See* Xu Decl. at ¶¶ 5 (mutual confidential disclosure agreement restricting the dissemination of Novartis's confidential and proprietary information relating to valsartan), 8 (API supply agreement prohibiting the disclosure of any business, commercial, or technical information or data disclosed in connection with the business relationship between Sandoz and the ZHP Parties), and 12-14 (confidentiality provision between MacLeods and the ZHP Parties in the parties' terms and conditions that continues to prohibit the disclosure of the parties' research, development, data and results, and scientific and technical strategies following the expiration of the parties' obligations under the confidentiality disclosure agreement).

21. These confidentiality agreements expressly prohibit the disclosure to third parties of the parties' confidential or proprietary information, including, but not limited to, business, commercial, or technical information and data disclosed by one party to the other in connection with their business relationship, or scientific or technical information. *See id.* at ¶¶ 8, 12-14.

22. The penalties for any party who discloses confidential information in contravention of these confidentiality agreements include, but are not limited to, liability for any damages incurred as a result of the disclosure and any equitable or

injunctive relief necessary for the injured party to be made whole. *See id.* at ¶¶ 6, 10, 13.

23. Disclosure of the Category 1 exhibits sought to be sealed here, without prior authorization from the customers with whom the communications occurred, would cause significant competitive harm by requiring the ZHP Parties to disregard the express intention of their customers to the contrary, breaching confidentiality agreements and thus jeopardizing customer relationships.

24. The clearly defined and serious injury that would result should the proposed Order to seal the Category 1 exhibits not be entered is the loss of longstanding customer relationships as a result of the ZHP Parties' breaching their customer agreements, as well as the risk of significant financial harm in the form of litigation costs and contract damages. The risk of this injury to the ZHP Parties is especially unwarranted since many of the challenged communications discuss non-U.S. DMF grade valsartan, which is irrelevant to the claims at issue in this litigation.

**B. The ZHP Parties' Legitimate Interest in Maintaining the Confidentiality of Exhibit 10 Because It Discloses Competitively Sensitive Information Regarding Prospective Business Agreements (the Category 2 Document)**

25. Likewise, the ZHP Parties have a legitimate interest in maintaining the confidentiality of documents that disclose the ZHP Parties' competitively sensitive, non-public information regarding their prospective business agreements, development contracts, and cost calculations.

26. The sole Category 2 document at issue is ZHP02628144, which consists of a series of non-public communications between the ZHP Parties and a potential business partner from November-December 2017 regarding a draft valsartan synthesis process development contract. *See* Xu Decl. ¶¶ 16-17.

27. In these emails, the ZHP Parties and their intended business partner discuss the draft agreement and proposed revisions to the contact prior to its implementation, including whether the agreement should include four pharmaceutical products not related to valsartan, and whether their intended business partner has the technical capability to include the additional products subject to the ZHP Parties' specifications. *See id.* at ¶ 16. The communications also discuss considerations for future collaborations and material cost calculations. *See id.* at ¶ 17.

28. The ZHP Parties have a legitimate interest in maintaining the confidentiality of communications with its potential business partners prior to execution of their process development contracts. This Court has previously concluded that business agreements that disclose the ZHP Parties' development costs and proprietary information may be properly sealed. *See* May 24 Order at ¶ 18 (granting motion to seal 2010 business agreement between ZHP and Shanghai Syncores that detailed ZHP's proprietary manufacturing processes prior to implementation and revealed ZHP's development costs, and where "[Plaintiffs] do

not explain how unsealing this document will advance public understanding of the valsartan contamination.").

29. The clearly defined and serious injury that would result should the proposed Order to seal ZHP02628144 not be entered is the disclosure of the ZHP Parties' contract negotiations with potential business partners prior to execution, and project development costs to its direct competitors, many of whom are defendants in this litigation. Such disclosure would compromise the future integrity of the ZHP Parties' project negotiations, while allowing its direct competitors to take advantage of the ZHP Parties' business strategies and cost analyses.

### C. The ZHP Parties' Legitimate Interest in Maintaining the Confidentiality of Exhibits 9, 14, 15, and 16 Because They Disclose Proprietary Testing Processes Related to Irbesartan (the Category 3 Documents)

30. Finally, the ZHP Parties have a legitimate interest in maintaining the confidentiality of non-public, internal communications that disclose their proprietary research and development information, including their proprietary testing processes, pursuant to Paragraph 9(M) of the Protective Order.

31. This Court, and courts construing New Jersey law, have repeatedly recognized the need to protect from disclosure confidential research, development, product testing, and other trade secret information involving pharmaceutical manufacturers to protect a litigant's standing in the marketplace. *See, e.g., Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *3

(D.N.J. Dec. 6, 2018) (stating, "this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers"); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 667 (affirming magistrate judge's denial of motion to unseal documents that contained information relating to defendant's ANDA, DMF, processes, formulations, and testing); *Valeant Pharm. Luxembourg S.à r.l. v. Actavis Labs. UT, Inc.*, No. 2:16-cv-4344, 2018 WL 1469050, at *3 (D.N.J. March 26, 2016) (same); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at *2 (D.N.J. Aug. 7, 2015) (sealing documents that producing party designated highly confidential because they "contain or reflect … highly proprietary business information regarding the development, formulation, manufacture and sales of ANDA products"); *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 U.S. Dist. Lexis 212, at *6-8 (D.N.J. Jan. 3, 2017) (sealing confidential research and development processes and information as well as internal documents, such as laboratory notebooks).

32. Similarly, this Court has recognized the need to protect from disclosure internal communications and discussions regarding ZHP's internal testing processes and procedures where ZHP has "sufficiently rebutted the presumption of public

access by making a specific showing of competitive harm." *See In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.,* MDL No. 2875, Order Granting in Part and Denying in Part the ZHP Parties' Motion to Seal dated May 24, 2021 at 18-19 (Vanaskie, J.) (the "May 24, 2021 Order") (granting motion to seal internal notes regarding ZHP's process optimization strategies where disclosure "would result in significant competitive harm by allowing [competitors] to benefit from ZHP's proprietary research and development while the FDA restricts ZHP from exporting its products into the U.S. market.") (ECF No. 1269); *see also In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.,* MDL No. 2875, Special Master Order No. 47 dated Oct. 8, 2021 at 2 (Vanaskie, J.) (denying Plaintiffs' request to de-designate as confidential documents concerning Teva's testing methods and costs where "Teva demonstrated that this information is not shared with its competitors and is regarded as having economic significance.") (ECF No. 1616); *Novartis Pharms. Corp. v. Mylan Pharms., Inc.,* No. 06-2885 (MLC), 2008 WL 11383884 at *1-2 (D.N.J. Oct. 31, 2008) (granting motion to seal documents, including confidential communications with the FDA, where Novartis had a legitimate business interest in preventing the disclosure of confidential and proprietary information, and where disclosure of such information would result in competitors gaining an unfair competitive advantage in the marketplace).

33. As described in the Li Declaration, the Category 3 communications contain commercially sensitive, non-public, information regarding the ZHP Parties' proprietary testing as to irbesartan API, a different product than valsartan. The Category 3 communications focus on the ZHP Parties' testing of certain irbesartan compounds, which are unrelated to the claims at issue. These include test results relating to irbesartan intermediate compounds rather than the finished API product. *See* Li Decl. at ¶ 3. These also include pilot test and experiment results, which in essence rehearse the ZHP Parties' actual tests, and allow the ZHP Parties the opportunity to refine their actual testing approaches. *See id.* at ¶¶ 5-6.

34. Additionally, they include an investigation report that details the results of the ZHP Parties' preliminary investigation into certain technical changes observed during attempted process improvements and subsequent testing for possible impurities following the manufacture of irbesartan crude product, which were part of the ZHP Parties' efforts to optimize their irbesartan manufacturing processes. *See id.* at ¶ 4. This information is highly confidential, proprietary, and competitively sensitive because it reveals how the ZHP Parties sought to optimize their procedures for manufacturing irbesartan API by addressing certain technical changes observed during the attempted process improvements, and the specific tests conducted to investigate the changes, which were the result of significant research and development by ZHP. *See id.*

35. The clearly defined and serious injury that would result should the proposed Order to seal not be entered regarding these exhibits is that the ZHP Parties would suffer significant competitive harm as a result of the disclosure to their competitors of their proprietary testing procedures relative to irbesartan, a widely prescribed and used antihypertensive medication.

36. It is well-known that the pharmaceutical industry is a "highly competitive market where companies routinely attempt to discover a possible advantage over their competitors." *See Public Citizen Health Research Grp. v. NIH*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002); *see also United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165 GHK (SS), 2016 WL 6542729, at *4 (C.D. Cal. Mar. 14, 2016) ("In a field as competitive and technical as the pharmaceutical industry, success or failure will turn in large measure on innovation . . . .") (internal citation omitted).

37. As the Court is aware, many of the ZHP Parties' direct competitors are defendants in this MDL, while other competitors who are not could readily access this information if it were made publicly available. The disclosure of the Category 3 communications would be of significant competitive value to the ZHP Parties' many competitors in the generic drug marketplace, including, but not limited to, those named as defendants in this MDL, by allowing the ZHP Parties' direct competitors to implement and benefit from the ZHP Parties' research and development

information, and testing directed to optimizing irbesartan's manufacturing processes while the FDA restricts ZHP from exporting its products into the U.S. market, thereby providing a significant competitive advantage to the ZHP Parties' competitors. *See* Li Decl. at ¶¶ 3-6. Furthermore, such disclosure may well impede the ZHP Parties' ability to re-enter the U.S. market following the lifting of the current import ban. *See id.*

**D. There Is No Less Restrictive Alternative Available to Sealing the Challenged Exhibits**

38. There is no less restrictive alternative to moving to seal the ten exhibits. The ZHP Parties carefully analyzed all seventeen of the challenged exhibits to identify which information should be sealed, have agreed to de-designate seven (7) out of the seventeen challenged exhibits, and they seek to seal only those exhibits that cannot be de-designated because they implicate third party privacy interests or otherwise contain commercially sensitive or proprietary, non-public information regarding the ZHP Parties' testing procedures that was appropriately designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" by the ZHP Parties pursuant to the Protective Order. *See* Bonner Decl. at ¶ 12.

**E. There Is No Prior Order Sealing the Challenged Exhibits**

39. There is no prior Order sealing the exhibits, or the confidential information discussed therein. *See id.* at ¶ 13.

**F. Plaintiffs' Objections to Sealing the Challenged Exhibits**

40. Plaintiffs have objected to the ZHP Parties' sealing request on several grounds. *See* Bonner Decl. at ¶ 14. But Plaintiffs' contentions are incorrect and insufficient to de-designate the challenged exhibits.

41. First, Plaintiffs have objected to the ZHP Parties' request to seal Exhibits 4, 5, 6, and 7 on the grounds that confidential treatment is not justified under the Protective Order in light of their belief that the ZHP Parties have waived confidentiality as to Exhibits 4 and 6 (of which Exhibits 5 and 7 are duplicates), and that they appear to discuss matters of public knowledge. *See id.* at ¶ 15.

42. As stated above, *supra* note 1, the ZHP Parties dispute Plaintiffs' allegation that they waived confidentiality as to Exhibits 4 and 6 (let alone Exhibits 5 and 7), and this issue has been fully briefed and is *sub judice*. *See id.* at ¶ 16. The ZHP Parties maintain the appropriateness of their confidentiality designation of these exhibits as "RESTRICTED CONFIDENTIAL INFORMATION" pursuant to Paragraph 9(M) of the Protective Order. *See id.*

43. Nor have Plaintiffs asserted any basis for their assertion that these communications contain matters of public knowledge where, as stated herein *supra* ¶ 11, the communications discuss, respectively (1) the specific details of the return of valsartan API delivered to NIPBI, including details from a management meeting between NIPBI and the ZHP Parties; (2) various claims and actions levied against

Sandoz affiliates; and (3) chromatography testing results of the ZHP Parties' valsartan KSM communicated with the ZHP Parties' customer, MacLeods. *See* Xu Decl. ¶¶ 4, 7, and 11. The contents of these communications are not publicly known, but rather, represent confidential information exchanged pursuant to confidentiality agreements. *See id.* at ¶¶ 5, 8, 12.

44. Second, Plaintiffs have objected to the ZHP Parties' request to seal Exhibit 10 on the grounds that confidential treatment is not justified under the Protective Order because Plaintiffs allege that Exhibit 10 is a routine business communication that does not warrant sealing as a court record. *See* Bonner Decl. at ¶ 18. But Plaintiffs' characterization of Exhibit 10 as a "routine business communication" is meritless. As described in the Xu Declaration, Exhibit 10 contains non-public communications between the ZHP Parties and a potential business partner regarding proposed revisions to a draft valsartan synthesis process development contract, including whether to expand the agreement's provisions to encompass products unrelated to valsartan, as well as material costs and product specifications. *See* Xu Decl. at ¶¶ 16-17. This Court has previously concluded that business agreements disclosing the ZHP Parties' development costs and proprietary information may be properly sealed. *See* May 24 Order at ¶ 18.

45. Third, Plaintiffs have objected to the ZHP Parties' request to seal Exhibits 8, 9, 14, 15, and 16 on the grounds that confidential treatment is not justified

under the Protective Order in light of what they argue is the public's right to access them as court records. *See* Bonner Decl. at ¶ 20. But as the Third Circuit articulated in *Avandia*, the public's right to access court records is not paramount: it must be balanced against "various factors that courts may consider when determining whether good cause exists and, by extension, whether a protective order should issue." *See Avandia*, 924 F.3d at 671.

46. Plaintiffs have not articulated how the disclosure of the ZHP Parties' confidential information contained in Exhibits 8, 9, 14, 15, and 16 either safeguards public health or advances any current or immediate public health interest. *See* Bonner Decl. at ¶ 20.

47. Conversely, as outlined below, several of the *Avandia* factors weigh against disclosure of the challenged exhibits:

- The ZHP Parties produced Exhibits pursuant to a negotiated, valid confidentiality and protective order, with the assurances that any confidential information produced thereunder would remain confidential.

- Disclosure of information contained in the challenged exhibits to the ZHP Parties' direct competitors, including defendants in this MDL, would not promote fairness and efficacy—rather, it would risk and may result in competitive harm to the ZHP Parties from the disclosure of information of a proprietary and confidential nature never intended to be shared with others outside of the ZHP-affiliated companies, or information deliberately intended to be protected by enforceable confidentiality agreements.

- The authors of the Category 1 communications are employees of customers of the ZHP Parties—Novartis, Sandoz, and MacLeods—

> whose communications to the ZHP Parties were not intended for public disclosure, and, in fact, are protected by enforceable confidentiality agreements with the recipients.

*See* May 24, 2021 Order (ECF. No. 1269) (citing *Avandia*, 924 F.3d at 670).

48. For these and all of the foregoing reasons, the ZHP Parties' interest in preserving the confidential and proprietary nature of customer communications protected by robust confidentiality agreements, negotiations related to draft business agreements not intended for public dissemination, or internal communications relating to product testing with the goal of improving and optimizing manufacturing processes of one of the ZHP Parties' pharmaceutical APIs (in this instance, irbesartan API), outweighs any public interest in disclosing such information. *See id*.

49. The Court, having considered this matter pursuant to Local Civil Rule 5.3(c), and the submissions in support of the Motion to Seal, finds that the ZHP Parties have satisfied their burden of establishing under Local Civil Rule 5.3(c) and applicable case law that Exhibits 4, 5, 6, 7, 8, 9, 10, 14, 15, and 16 to Plaintiffs' Motion to Compel ought to be sealed by the ZHP Parties because they contain information properly designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" under the Protective Order.

50. Pursuant to the foregoing Findings of Fact and Conclusions of Law, and for good cause shown:

**IT IS** on this _____ day of _____, 2021, hereby

**ORDERED** that the ZHP Parties' Motion to Seal is hereby **GRANTED**; and

**IT IS FURTHER ORDERED** that Exhibits 4, 5, 6, 7, 8, 9, 10, 14, 15, and 16 to Plaintiffs' Motion to Compel shall be remain sealed, and that the portion of Plaintiffs' Motion to Compel that discloses confidential information contained therein also remain redacted.

**IT IS FURTHER ORDERED** that a copy of this Order shall be served on all counsel of record within ____ days of Plaintiffs' liaison counsel's receipt of this Order.

By the Court:

**Dated:_____**

_____
Hon. Thomas Vanaskie, (Ret.)
Special Discovery Master